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PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Jeffrey Marc Dayno, et al.

Serial No.: 10/767,025 Case 21311

Filed: January 29, 2004

For: COMBINATION THERAPY FOR THE  
TREATMENT OR PREVENTION OF MIGRAINE

Art Unit:  
1617

Examiner:  
Kim, Jennifer M.

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO RESTRICTION REQUIREMENT**

Sir:

This communication is in response to the Restriction Requirement dated September 29, 2004 setting forth a shortened statutory period for response ending October 29, 2004. Reconsideration and allowance of the above-identified patent application are respectfully requested. This application relates to the combination of a COX-2 selective inhibiting compound and a beta adrenergic blocking agent.

Claims 1 to 20 are pending in the application. The Examiner required restriction of these claims and an election of one of the following patentably distinct inventions:

- Group I: Claims 1 to 18, drawn to a method of treating or preventing migraine in a mammalian patient comprising administering a cyclooxygenase-2 selective inhibitor and a beta-adrenergic receptor blocking agent, calssified in class 514, subclass 406; and
- Group II: Claims 19 and 20, drawn to a pharmaceutical composition comprising a cyclooxygenase-2 selective inhibitor and a beta-adrenergic receptor blocking agent, calssified in class 514, subclass 406.

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Group I is hereby elected with traverse. Applicants also hereby elect the specie wherein the COX-2 selective inhibitor is etoricoxib (ARCOXIA<sup>TM</sup>) and the beta adrenergic blocking agent is timolol maleate (BLOCADREN<sup>®</sup>), with traverse. This election of a species is being made for purposes of facilitating the Examiner's search with the understanding that the election requirement will be withdrawn upon making a determination that an allowable generic claim exists.

Applicants submit that the examination of Claims 1 to 20 can be made without any serious burden on the part of the Examiner. As stated in MPEP §803 there are two criteria for a proper requirement for restriction between patentably distinct inventions: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is not required. Although Applicants agree that each of Groups I-II is patentably distinct over the other, Applicants submit the inventions are sufficiently related such that they impose no serious burden on the Examiner to search and examine the application. In fact, substantial economy of the Examiner's time can be realized by conducting a single search of the art and significant expense can be avoided on the part of the Applicants. Withdrawal of the Restriction Requirement is therefore respectfully requested.

Applicants respectfully submit that the application is in condition for allowance and passage thereto is earnestly requested. Any additional fees required in connection with this Amendment may be taken from Merck Deposit Account No. 13-2755. The Examiner is invited to contact the undersigned attorney at the telephone number provided below if such would advance the prosecution of the case.

Respectfully submitted,

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By [Signature] Date 22 OCT 04

Date: October 22, 2004

By [Signature]  
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